SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

STUDY INFORMATION

Protocol Title:

Comparison of conventional face-to-face dietary education with online self-learning for women with GDM – a pilot study

Principal Investigator:

Dr Han Wee Meng, Nutrition & Dietetics Department, KK Women's and Children's Hospital, 100 Bukit Timah Road Singapore 229899, 6394 1640

PURPOSE OF THE RESEARCH STUDY

You are being invited to participate in a research study. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document to take home with you.

The purpose of this study is to determine the *practicality and acceptability* of using telehealth in the care of women with GDM by providing a *self-learning alternative via an online portal,* compared to face-to-face dietary education with a dietitian at the hospital. We hope to (1) enable more women to be provided with the necessary dietary education and (2) demonstrate that this method of dietary intervention will be able to provide care that would be comparable to the conventional outpatient clinic setting.

You were selected as a possible participant in this study because you have undergone an oral glucose tolerance test, which diagnosed you with gestation diabetes mellitus (GDM).

This study will recruit 50 participants from KK Women's and Children's Hospital (KKH).

STUDY PROCEDURES AND VISIT SCHEDULE

If you agree to take part in this study, you will be randomised to the conventional face-to-face dietary education with a dietitian at the outpatient clinic at the hospital (standard group) or the telehealth with online self-learning (intervention group). Randomisation means assigning you to one of the 2 groups by chance. The randomisation will be done by a research coordinator, who will assign your grouping based on a number sequence.

If you agree to take part in this study, you will be asked to undergo a dietary education session to teach you on how to manage your GDM, receive dietary reviews by a dietitian and complete a series of questionnaires. Your participation in the study will last 12 to 16 weeks or until the completion of your pregnancy. You will need to check your blood glucose level at least once a week as part of the standard care for GDM and be followed up by the dietitian every 2 to 4 weeks in clinic (standard group) or via telehealth (intervention group) until the completion of your pregnancy. You will visit the doctor's office as per your usual routine in the course of the study.

Information will also be collected from you or your medical records and this include: your age, nationality, education level, employment status, family history, personal history (including history of GDM), obstetric history, your pre-pregnancy weight, current weight and height. In order to assess the feasibility of telehealth, information on transport cost to visit the hospital, cost of taking time-off from employment will also be collected from you.

After delivery of your baby, information on birth outcomes will be obtained. These include your baby's birth weight, the type of delivery (whether via normal vaginal delivery or caesarean section), and if your baby experienced any low blood glucose level (defined as blood glucose level below 3.0mmol/L). Your total weight gain for the pregnancy will also be determined from your medical records.

Example of schedule of visits and procedures*:

Visit no.	Standard group	Intervention group
Visit 0	Routine doctor's visit (5-10minutes)	Routine doctor's visit (5-10minutes) Online self-learning at home (up to 60minutes)
Visit 1 (week 1)	Face-to-face dietary education session (45-60minutes)	Telehealth consult (20-25minutes)
Visit 2 (week 3-5)	Face-to-face dietitian review, to be arranged on same day as routine doctor's clinic visit (30-40minutes)	Telehealth consult (10-15minutes)
Visit 3 (week 7-9)	Face-to-face dietitian review, to be arranged on same day as routine doctor's clinic visit (30-40minutes)	Telehealth consult (10-15minutes)
Final visit (week 10-11)	Face-to-face dietitian review, to be arranged on same day as routine doctor's clinic visit (30-40minutes)	Telehealth consult (10-15minutes) Online self-learning at home (up to 30minutes)

*Duration of visit is subjected to each individual. The following above contains the estimated visit duration.

Any individually-identifiable data obtained during the course of this study will be stored and used only for the purposes of this study. These data will not be used for future research.

YOUR RESPONSIBILITIES IN THIS STUDY

If you agree to participate in this study, you should

- Follow the dietary advice and monitor your blood glucose levels
- Keep your study appointments or tele-consult appointments. If it is necessary to miss an appointment, please contact the study staff to reschedule as soon as you know you will miss the appointment.
- Inform the Principal Investigator as soon as possible about any side effects that you may have encountered.
- Be prepared to visit the hospital up to 4 times if you are in the standard group or 1 time in the intervention group, and undergo all the procedures that are outlined above.

WHAT IS NOT STANDARD CARE OR EXPERIMENTAL IN THIS STUDY

The study is being conducted because telehealth approach is not yet proven to be a standard mode of service delivery in participants with GDM. We hope that your participation will help us to determine whether telehealth is equal to existing face-to-face consultations.

Use of randomization is only done for research studies. Although face-to-face consultations may be part of standard medical care, in this study this is being performed for the purposes of the research.

POSSIBLE RISKS, DISCOMFORTS AND INCONVENIENCES

- The telehealth intervention may involve risks to the participant, which are unforeseeable.
- There may be an increased number of contact points for the patients.
- There may be potential risks from disclosures associated with transmitting or storing of blood glucose profile.

POTENTIAL BENEFITS

Your participation in this study will add to our knowledge about the use of telehealth. There may be less inconvenience to you where you will not need to attend face-to-face dietary education and consultations at the hospital.

ALTERNATIVES

If you choose not to take part in this study, the alternative is to have what is considered standard care for your condition. In our institution this would be to attend a face-to-face dietary education (duration 45-60minutes) with a dietitian at the outpatient clinic at the hospital and subsequently, face-to-face dietitian review. (duration 30-40minutes).

This alternative procedure has the following potential benefits:

- Face-to-face interactions with healthcare professionals

and the following potential risks:

- Involves time away from home/ workplace, and additional time spent in clinic consultations

COSTS OF PARTICIPATION

If you take part in this study, the following will be performed at no charge to you: costs associated with use of telehealth or face-to-face sessions with a dietitian, blood glucometer, test strips and lancets. These costs will be borne by the iPRAMHO research grant.

If you take part in this study, you will have to pay for the following: your doctor's consultations and all associated scans/blood tests/ investigations ordered by your doctor.

INCIDENTAL FINDINGS

In the case of an "incidental finding" (i.e. any abnormality that we did not expect to see in this study or unrelated to the purpose of this study), we will not re-identify and give you any results from the research.

PARTICIPANT'S RIGHTS

Your participation in this study is entirely voluntary. Your questions will be answered clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or her representative and will be contacted for further consent if required.

By signing and participating in the study, you do not waive any of your legal rights to revoke your consent and withdraw from the study at any time.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation at any time without prejudice to you or effect on your medical care. If you decide to stop taking part in this study, you should tell the Principal Investigator.

If you withdraw from the study,
- You will have to continue to follow-up with a dietitian through the conventional way and bear the associated costs.
- You will need to return all the study-related supplies.

However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the study.

Your doctor, the Principal Investigator and/or the Sponsor of this study may stop your participation in the study at any time for one or more of the following reasons:
- Failure to follow the instructions of the Principal Investigator and/or study staff.
- Failure to complete the self-learning modules and/ or perform the self-blood glucose monitoring at home
- Decline to answer the tele-consultations
- The Principal Investigator decides that continuing your participation could be harmful.
- You need treatment not allowed in the study.
- The study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the trial substance or research procedure given under the plan for the research study, our institution will provide you with the appropriate medical treatment.

Payment for management of the normally expected consequences of your treatment will not be provided by the hospital.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study will involve the collection of Personal Data. Personal Data collected for this study will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available. Only your Investigator(s) will have access to the confidential information being collected.

However, Regulatory Agencies, Institutional Review Board and Ministry of Health will be granted direct access to your original medical records to check study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by KKH, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties.

“Personal Data” means data about you which makes you identifiable (i) from such data or (ii)

from that data and other information which an organisation has or likely to have access. Examples of personal data include medical conditions, medications, investigations and treatment history.

Research arising in the future, based on this “Personal Data”, will be subject to review by the relevant institutional review board.

Data collected and entered into the Data Collection Form are the property of KKH. In the event of any publication regarding this study, your identity will remain confidential.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact the Principal Investigator, Dr Han Wee Meng at 63941640.

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 6323 7515 during office hours (8:30 am to 5:30pm).

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM

Details of Research Study

Protocol Title:

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Principal Investigator:

Dr Han Wee Meng, Nutrition & Dietetics Department, KK Women's and Children's Hospital, 100 Bukit Timah Road Singapore 229899, 6394 1641

I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

I have fully discussed and understood the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to ask questions about this study and have received satisfactory answers and information.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for the above participant to participate in the proposed research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature/ Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained in a language understood by him/ her and clearly understands the nature, risks and benefits of his/ her participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant or legal representative thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained and clearly understands the nature, risks and benefits of his/ her/ his ward's/ her ward's participation in the study.

_____ _____ _____
Name of Investigator/ Person obtaining consent Signature Date